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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,128	12/15/2003	Michael John Rutter	CHM-010	5727
38155	7590	11/30/2004	EXAMINER	
HASSE GUTTAG & NESBITT LLC 7550 CENTRAL PARK BLVD., MASON, OH 45040			PATEL, NIHIR B	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/737,128		RUTTER, MICHAEL JOHN	
	Examiner		Art Unit	
	Nihir Patel		3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12.15.2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03.22.2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 through 11, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Beck, Jr. et al. US Patent No. 5,339,809. Referring to claim 1, Beck discloses a method of inserting a cricothyroidal endotracheal device between the cricoid and thyroid cartilages for treatment of chronic respiratory disorders that comprises a short distal section of tubing (see figure 2); an intermediate section of tubing (see figure 2); a pre-formed obtuse angle bend in the tube between the distal and intermediate sections (see figure 2); an elongated proximal section of tubing (see figure 2); a pre-formed abrupt bend in the tube between the intermediate and proximal sections (see figure 2); and an inflatable cuff 16 integrated into the distal section of tubing (see figure 2).

Referring to claim 3, Beck discloses an apparatus wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of the tube at an angle of from about 80 to about 95 degrees (see figure 2).

Referring to claim 4, Beck discloses an apparatus wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of the tube at approximately a right angle (see figure 2).

Referring to claim 5, Beck discloses an apparatus wherein the distal section, the intermediate section, and the proximal section extend in the same general plane (see figure 2).

Referring to claim 6, Beck discloses an apparatus wherein the proximal section is substantially rectilinear in formation (see figure 2).

Referring to claim 7, Beck discloses an apparatus wherein the distal section and the intermediate section are substantially rectilinear in formation (see figure 2).

Referring to claim 8, Beck discloses an apparatus wherein the obtuse-angle bend in the tube is from about 105 to about 130 degrees (see figures 1 and 2).

Referring to claim 9, Beck discloses an apparatus wherein the obtuse angle bend in the tube is from about 110 to about 120 degrees (see figures 1 and 2).

Referring to claim 10, Beck discloses an apparatus wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of tube at approximately a right angle (see figure 2).

Referring to claim 11, Beck discloses an apparatus wherein the proximal section, the distal section, and the intermediate section are substantially rectilinear in formation (see figure 2).

Referring to claim 15, Beck discloses an apparatus wherein the inflatable cuff securely locates the distal section in a patient's trachea and substantially prevents leakage of air back out the patient's mouth during positive pressure ventilation (see figure 2).

Referring to claim 17, Beck discloses a method of inserting a cricothyroidal endotracheal device between the cricoid and thyroid cartilages for treatment of chronic respiratory disorders that comprises a short distal section of tubing (see figure 2); an intermediate section of tubing

(see figure 2); a pre-formed obtuse-angle bend in the tube between the distal and intermediate sections (see figure 2); an elongated proximal section of tubing (see figure 2); a pre-formed abrupt bend in the tube between the intermediate and proximal sections (see figure 2); and an inflatable cuff 16 integrated into the distal section of tubing (see figure 2); wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of the tube at an angle of from about 80 to about 95 degrees, and the obtuse angle bend interconnects the distal section and the intermediate section along the length of the tube at an angle from about 105 to about 130 degrees; and wherein the distal section, the intermediate section, and the proximal section extend in the same general plane and are substantially rectilinear in formation (see figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 12, 18, 19, 20, 23, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr., et al. US Patent No. 5,339,809 in view of Nye US Patent No. 5,590,647. Beck discloses the applicant's invention as claimed with the exception of providing a flexible tube that is made of a thermoplastic material preformed to the shape described. Nye discloses a method of providing anesthesia with a specialized tracheal tube that does provide a flexible tube that is made of a thermoplastic material preformed to the shape described. Therefore it would have been obvious to modify Beck's invention by providing a flexible tube

that is made of a thermoplastic material preformed to the shape described in order to prevent the patient from getting ill.

Claims 13, 14, 16, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr., et al. US Patent No. 5,339,809 in view of Joseph US Patent No. 5,582,167. Beck discloses the applicant's invention as claimed with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Joseph discloses methods and apparatus for reducing tracheal infection using subglottic irrigation, drainage and servo-regulation of endotracheal tube cuff pressure that does provide a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Therefore it would have been obvious to modify Beck's invention by providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate in order to assist in breathing.

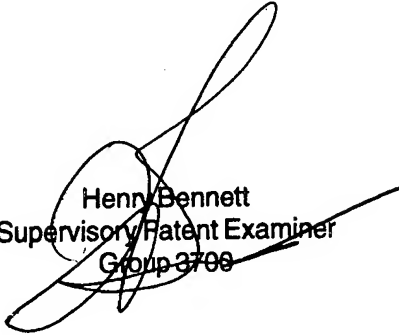
In reference to claims 23 and 26, after reviewing the applicant's specifications the examiner discovered that the applicant has not established any criticality on why the ratio between the length of the distal section to the length of the intermediate section must be between 1.0 to about 2.0 as stated in claim 23 and 1.2 to about 1.8 as stated in claim 26 and the ration between the length of the proximal section to the length of the distal section must be between 2.0 to about 4.0 as stated in claim 23 and 2.5 to about 3.5 as stated in claim 26. Since the applicant has not established any criticality the ratio are considered a simple matter of design choice.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (571) 272 4791.

NP
November 19th, 2004



Henry Bennett
Supervisory Patent Examiner
Group 3700